SIMMONS
CLINICAL CARE

LF latex free

765000S

Not made with natural rubber latex.

CLINICAL PLUS ALTERNATING PRESSURE MATTRESS SYSTEM WITH ACTIVE SENSOR TECHNOLOGY

USER MANUAL

Important: Do not operate the Mattress System without first reading and understanding this manual! Save this manual for future use.

Info: The most current version of this manual can be found online at www.grahamfield.com.

765000S-INS-LAB-RevC14

CONTENTS

INTRODUCTION 3
INTENDED USE OF THIS DEVICE 3
CONTRAINDICATION 3
IMPORTANT SAFETY PRECAUTIONS 4
DANGER 5
WARNING 6
NOTICE 7
EQUIPMENT SYMBOLS 8
PRODUCT DESCRIPTION 9
PUMP AND MATTRESS SYSTEM 9
PUMP: FRONT 10
PUMP: REAR 10
PUMP: FRONT PANEL 11
INSTALLATION 15
UNPACKING 15
PUMP AND MATTRESS SETUP 16
OPERATION 18
GETTING STARTED 18
QUICK DISCONNECT 18
TRANSPORT CAP 19
CPR FUNCTION 19
MAINTENANCE 20
CLEANING 20
GENERAL MAINTENANCE 20
FUSE REPLACEMENT 21
AIR FILTER REPLACEMENT 21
STORAGE 21
TROUBLESHOOTING 22
SERVICE 22
SPECIFICATIONS 23
ONE (1) YEAR LIMITED WARRANTY 24
APPENDIX A: EMC INFORMATION 25

SIMMONS Clinical Care products manufactured by GF Health Products, Inc. under license from the trademark owner, Dreamwell, Ltd., a subsidiary of Simmons Bedding Company, Atlanta, Georgia. SIMMONS is a trademark of Dreamwell, Ltd. a subsidiary of Simmons Bedding Company.
© 2013 Dreamwell, Ltd. All rights reserved.

Graham-Field is a registered trademark of GF Health Products, Inc.
GF Health Products, Inc. is not responsible for typographical errors. All illustrations, specifications, packaging and warranties contained in this catalog are based on the latest product information available at the time of printing. The most current product information can be found online at www.grahamfield.com.

INTRODUCTION

Use this manual for set-up and operation of the SIMMONS™ Clinical Care 765000S Clinical Plus Alternating Pressure Mattress System with Active Sensor Technology. Read all instructions before using the mattress system. Save this manual for future reference.

INTENDED USE OF THIS DEVICE

The intended use of the SIMMONS™ Clinical Care 765000S Clinical Plus Alternating Pressure Mattress System with Active Sensor Technology is:

- Aid in the treatment of pressure ulcers while optimizing user comfort.
- Pain management as prescribed by a physician.
- As described above, in either a homecare or long-term care setting.

Contraindication

⚠ **WARNING: DO NOT use this product in the presence of flammable anesthesia. There is a possible fire hazard when this product is used with certain oxygen delivery equipment.**

Use nasal cannula, face mask, or 1/2 length oxygen tent to deliver oxygen in the presence of this product.

DO NOT use a full length oxygen tent that extends past the top surface of the mattress with this product.

IMPORTANT SAFETY PRECAUTIONS

The safety statements presented in this chapter refer to the basic safety information that should be observed by those using this Mattress System. There are additional safety statements in other chapters or sections, which may be the same as or similar to the following, or specific to the operations.

⚠ **DANGER: Indicates an imminent hazard situation that, if not avoided, will result in death or serious injury.**

⚠ **WARNING: Indicates a potential hazard situation or unsafe practice that, if not avoided, could result in death or serious injury.**

⚠ **CAUTION: Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor or moderate personal injury.**

▲ **NOTICE: Indicates a potential hazard or unsafe practice that, if not avoided, could result in product or property damage.**

Info: Provides application recommendations or other useful information to ensure that you get the most from your product.

DANGER

To reduce the risk of electrocution:

⚠ **DANGER: Always unplug this product immediately after use.**

⚠ **DANGER: Do not use this product while bathing.**

⚠ **DANGER: Do not place or store this product where it can fall or be pulled into a tub or sink.**

⚠ **DANGER: Do not place this product in or drop into water or other liquid.**

⚠ **DANGER: Do not reach for a product that has fallen into water. Unplug it *immediately*.**

WARNING

To reduce the risk of burns, electrocution, fire, or personal injury:

⚠ **WARNING: Use this product only as intended and described in this manual. Do not use attachments or accessories not recommended by Graham-Field.**

⚠ **WARNING: Do not leave this product unattended when plugged in.**

⚠ **WARNING: Always use close supervision when this product is used by, on, or near children or those who require close supervision.**

⚠ **WARNING: Never operate this product if:**

a) **it has a damaged cord or plug,**
b) **it is not working properly,**
c) **it has been dropped or damaged, or**
d) **it has been dropped into water.**

Return the product to your Graham-Field authorized distributor.

⚠ **WARNING: Keep the cord away from heated surfaces.**

⚠ **WARNING: Never block the air openings of this product or place it on a soft surface, such as a bed or couch, where the openings may be blocked. Keep the air opening free of lint, hair, and other similar particles.**

⚠ **WARNING: Never drop or insert any object into any opening or hose.**

⚠ **WARNING: Connect this product *only* to a properly grounded power outlet.**

⚠ **WARNING: Maximum patient weight capacity for this product is 400 lb (189 kg), EVENLY DISTRIBUTED.**

⚠ **WARNING: Notice for California Customers- California Proposition 65 WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive or developmental harm.**

⚠ **WARNING: Patient entrapment with bed side rails may cause injury or death. The bed frame and its components, including the mattress, bed side rails, head and foot board, bedding, and any accessories added to the bed, can all affect the risk of entrapment. Thorough patient assessment and monitoring are necessary to reduce the risk of entrapment, including establishing whether the use of a bed rail is in the best interest of the patient. Read and understand the User Manual before using this equipment. Graham-Field product manuals are available online at www.grahamfield.com.**

Visit the FDA's Bed Safety page at www.fda.gov to learn more about the risks of entrapment. It is the responsibility of the facility and provider to be in compliance with these guidelines. Refer to user manuals for beds and rails for additional product safety information.

After any adjustment, repair or service, and before use, ensure all attaching hardware is securely tightened. Bed rails with dimensions different than the original equipment specified by the bed manufacturer may not be interchangeable and may result in entrapment or other injury.

NOTICE

▲ **NOTICE: The pump can be used only with the accompanying mattress. Do not use it for any other purpose.**

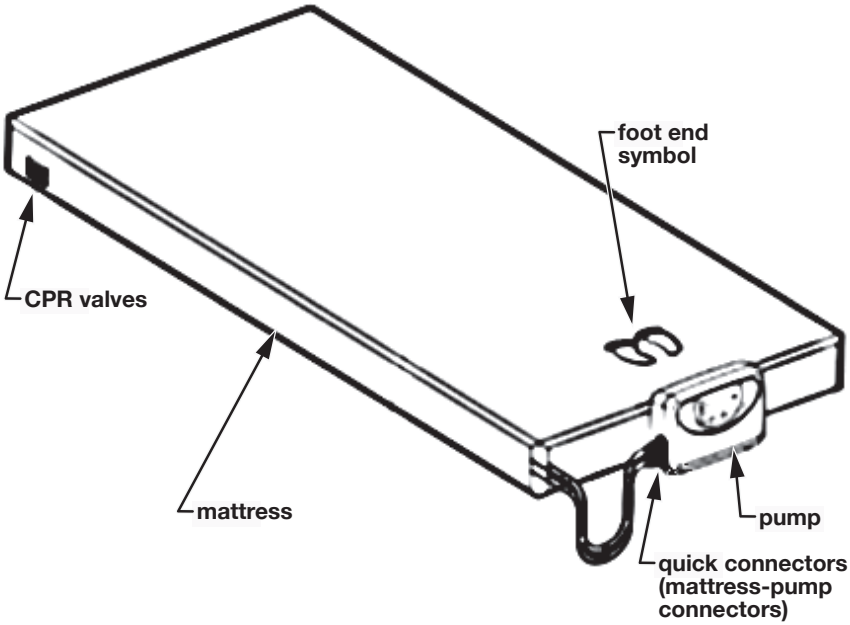
EQUIPMENT SYMBOLS

	Manufacturer
	"BF"symbol: Indicates that this product is in accordance with the degree of protection against electric shock for type BF equipment
	Functional earth (for UL only)
	Attention! Read the instructions!
	Disposal of Electrical & Electronic Equipment (WEEE): Do not treat this product as household waste. For more detailed information with regard to returning and recycling this product, please consult your local city office, household waste disposal service, or Graham-Field authorized distributor.
	Consult operating instructions
	Class II (for UL only)

The system has been tested and successfully approved with the following standards:		
CE	**EN 60601-1, EN 60601-1-2, EN 550011 Class B, IEC61000-3-2, IEC61000-3-3**	
For U.S. and Canada only		
E305034 53DG		**Medical Equipment: Air Pump with respect to electrical shock, fire and mechanical hazards only in accordance with UL60601-1 and CAN/CSA C22.2 No. 601.1**

PRODUCT DESCRIPTION

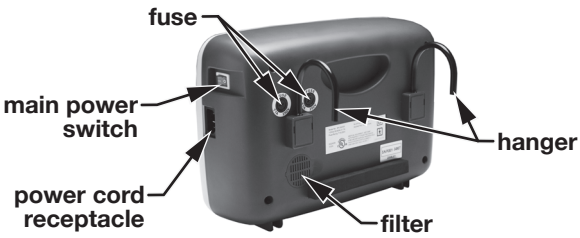
PUMP AND MATTRESS SYSTEM



pump and mattress system

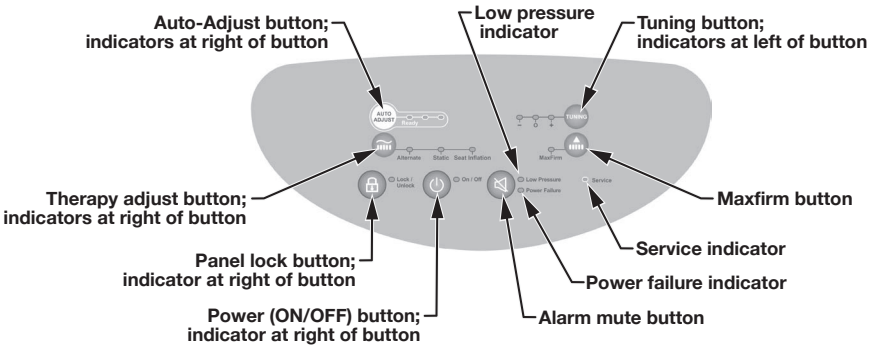
PUMP: FRONT

PUMP: REAR



PUMP: FRONT PANEL

Front panel of pump is shown below. Descriptions of buttons and indicators follow.


Auto-Adjust button; indicators at right of button
Low pressure indicator
Tuning button; indicators at left of button
Therapy adjust button; indicators at right of button
Maxfirm button
Service indicator
Panel lock button; indicator at right of button
Power failure indicator
Power (ON/OFF) button; indicator at right of button
Alarm mute button

Front panel, first row

Auto-Adjust button: The auto-adjust button adjusts the mattress pressure automatically based on the patient's weight. To remind the user that the auto-adjust process is ongoing, the auto-adjust indicator LEDs will periodically flash from left to right until the Ready LED illuminates to show the process is complete. Three conditions trigger the auto-adjust function:

1. Press the auto-adjust button for two seconds; the mattress system automatically readjusts pressure setting.
2. When initial mattress inflation is complete, the mattress system automatically starts the auto-adjust function.
3. When the mattress system detects a significant change in patient's weight on the mattress (e.g. patient egress or ingress), the system automatically starts the auto-adjust function.

When auto-adjust is complete, the Ready indicator will illuminate. To disable the auto-adjust function, press the auto-adjust button until auto-adjust indicators de-illuminate.

Info: During the auto-adjust operation, it is normal for the mattress system to cycle through a series of inflation and deflation.

Tuning button: The tuning button fine-tunes the mattress system's auto-adjusted pressure. Three tuning settings are available:

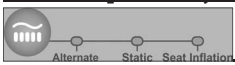
0 System auto-adjusted pressure

- One level softer than auto-adjusted pressure

+ One level firmer than auto-adjusted pressure

Info: The tuning function is only available in alternate and static therapy modes.

Front panel, second row



Therapy adjust button: The therapy adjust button selects the therapy mode. After power-up, the system automatically inflates the mattress, auto-adjusts the pressure, and enters alternate therapy mode. To then cycle among the therapy settings, press the therapy adjust button to select static therapy mode; press again to select alternate + seat inflation therapy mode; press again to select static + seat inflation therapy mode; press again to select alternate therapy mode, etc.

Alternate: Each tube fills for 10 minutes, then deflates for 10 minutes, alternately to the next tube. When selected, the alternate indicator illuminates.

Static: The pressure inside all tubes is adjusted to the same pressure. When selected, the static indicator illuminates.

Alternate + Seat Inflation: For use when the head is raised, to increase pressure under the buttocks — in alternating pressure therapy mode. When selected, both the alternate and seat inflation indicators illuminate.

Static + Seat Inflation: For use when the head is raised, to increase pressure under the buttocks — in static therapy mode. When selected, both the static and seat inflation indicators illuminate.

Maxfirm button: The pump will automatically enter maxfirm mode every time the power is turned on. Maxfirm mode ensures the pump is able to reach its maximum operating pressure. Maxfirm mode will last for 20 minutes, and then the system will automatically enter auto-adjust mode. To disable maxfirm mode, press the maxfirm button. When enabled, the maxfirm indicator, at left of button, illuminates.

Front panel, third row

Panel lock button: The panel lock button sets the panel lock to protect the panel settings from accidental change. Press for two seconds to lock; press FIRMLY for two seconds to unlock. After the panel has been untouched for five minutes, the panel lock locks automatically. When the panel is locked, the panel lock indicator will illuminate.

Power (ON/OFF) button: The power button turns power to the mattress system ON or OFF. Press to turn ON; press to turn OFF. When power is on, the power (ON/OFF) indicator will illuminate. When power is turned OFF, the mattress system will slowly deflate.

*Info: Main power switch on side of pump, previously shown in **PUMP: REAR**, must be ON in order for the front panel power button to function.*

Alarm Mute button: The alarm mute button temporarily suspends the LED indicator and buzzer when either the low-pressure alarm or power failure alarm is activated. Should the problem not be resolved within three minutes, the alarm will resume.

Low Pressure **Low pressure indicator:** The low pressure indicator (yellow LED) illuminates, and the alarm sounds, when an abnormally low pressure level occurs. If the low pressure indicator persistently illuminates inappropriately:

1. Check to ensure all connections are properly and securely connected per installation instructions.
2. Check for any leakage (tubes or connecting hoses). If necessary, contact your Graham-Field authorized distributor to replace any damaged tubes or hoses.
3. If problem persists, contact your Graham-Field authorized distributor.

Info: Sometimes the low pressure indicator will illuminate when a patient gets up to leave the bed. This is normal. The indicator will turn off automatically after a short time.

The low pressure indicator will illuminate until the low-pressure condition is resolved.

Power Failure **Power failure indicator:** The power failure indicator illuminates, and the alarm sounds, when there is a power failure. Depress the alarm mute button to disable both alarm and LED.

Service **Service indicator:** Mechanical failure, service required; contact your Graham-Field authorized distributor.

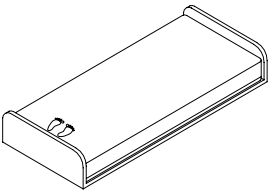
INSTALLATION

UNPACKING

1. Carefully remove all components from the carton.
2. Inspect all components.
3. If damage is evident to the contents, please notify the carrier and your Graham-Field authorized distributor.

PUMP AND MATTRESS SETUP

1. Place the mattress on top of the bed frame; ensure that the foot end symbol faces up at foot end as shown at right. Secure mattress to bed with straps.



2. Fold open the wire hangers on the back of the pump as shown at right.

3. Either hang the pump on the bed's foot end, as shown at right, or place the pump on a flat surface easily accessible to the caregiver and/or doctor.

▲ **NOTICE: Place the device in a position where the caregiver and/or doctor can access it easily.**

4. Connect the mattress-pump air hose quick connector; ensure that the connector has clicked securely into place before continuing.

▲ **NOTICE: Ensure the air hoses are not kinked or tucked under the mattress.**

⚠ **WARNING: Locate all cords so that they will not be stepped on, tripped over, or otherwise subjected to damage or stress.**

⚠ **WARNING: Do not use a household extension cord if the electrical cord does not reach the power outlet. Use of an improper extension cord could result in fire and electric shock. If an extension cord must be used, use a three conductor cord with ground, properly wired, in good electrical condition, and keep it as short as possible.**

⚠ **WARNING: Ensure that the local power voltage is appropriate for the pump unit.**

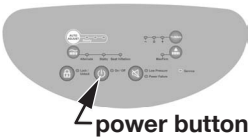
5. Plug the power cord into a properly grounded electrical outlet.

OPERATION

GETTING STARTED

1. Turn the main power switch to the ON position.

2. Press the front panel power button. The power indicator will illuminate.



Info: The mattress system will automatically enter maxfirm mode for the quickest inflation at set-up; when inflated, it will then automatically enter auto-adjust mode to select the appropriate pressure.

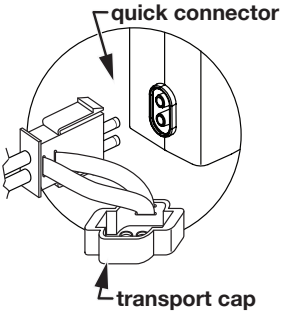
3. The pump will begin delivering air into the mattress. The low pressure indicator and the maxfirm indicator will illuminate for approximately twenty minutes until the mattress is fully inflated.
4. Upon inflation, the system will automatically enter auto-adjust mode to automatically select the appropriate pressure according to the patient's weight. The auto-adjust indicator LEDs will flash from left to right, and the system will cycle through inflation and deflation, until the Ready LED illuminates to show the process is complete, and the mattress system automatically enters alternate therapy mode.
5. Replace all sheets, blankets, and pillows on the bed.
6. You can now adjust therapy modes or tuning. Please see earlier section, **PUMP: FRONT PANEL**, for a complete description of available adjustments, buttons and indicators.

QUICK DISCONNECT

Pull the power plug from the wall connector to disconnect the device quickly.

TRANSPORT CAP

In case of power failure or transport: Disconnect the quick connector and cap the mattress with the transport cap to slow deflation.

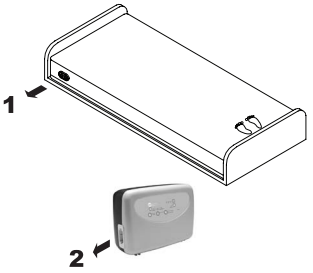


Info: This system is equipped with cell-on-cell technology to provide added support and prevent bottoming out in the event of a power failure. Lower cells will hold air for approximately eight hours.

CPR FUNCTION

If CPR must be performed on the patient while the mattress is in use, to immediately deflate the mattress, either:

1. Pull the CPR valves from the mattress in the location of the arrow shown at right, or
2. Disconnect the quick connector from the pump in the location of the arrow shown at right.



MAINTENANCE

CLEANING

⚠ **WARNING: To reduce the risk of increased bacterial growth, infection, illness, or injury from contamination, thoroughly clean and dry the mattress system before use and as necessary during use as follows:**

Pump: Wipe the pump with a clean, damp cloth and mild detergent, and keep it away from dust. Air dry.

▲ **NOTICE: Do not use phenolic products or corrosive or powdered cleansers to clean the pump.**

▲ **NOTICE: Do not immerse or soak the pump.**

Mattress: Wipe the mattress unit with a clean, damp cloth and mild detergent. The mattress may also be cleaned using a 10% solution of sodium hypochlorite (bleach) diluted in water. Air dry all parts thoroughly before use.

▲ **NOTICE: Do not use phenolic products to clean the mattress.**

▲ **NOTICE: After cleaning, air dry the mattress without direct exposure to sunlight.**

GENERAL MAINTENANCE

1. Check main power cord for abrasion or excessive wear.
2. Check mattress cover for signs of wear or damage. Ensure mattress cover and tubes are connected correctly.
3. Check airflow from the air hose connector. The airflow should alternate between each connector every half-cycle time while in alternating mode.
4. Check the air hoses for any kink or break. For replacement, please contact your Graham-Field authorized distributor.

Fuse replacement

tool needed: small screwdriver

1. If you suspect a blown fuse, disconnect the plug from the wall outlet immediately.
2. Use a small screwdriver to remove the cover of the fuse holder (fuse locations are shown in picture at right).
3. Insert a new fuse of the correct rating (T1A/250V, VDE approved).
4. Replace the fuse holder cover. Ensure that fuse holder cover is securely installed.

Air filter replacement

tool needed: small screwdriver

1. Use a small screwdriver to remove the air filter plate located at rear of pump (filter location is shown in picture at right).
2. Remove the filter. The filter is reusable, if not torn, and can be washed gently with a mild detergent and water. Dry the filter before use.
3. Replace the filter and cover. Ensure that filter cover is securely installed. Replace the air filter regularly if it is gray, torn, or the environment is dirty.

STORAGE

1. Lay the mattress out flat and upside down.
2. Roll from the head end toward the foot end.
3. Stretch the foot-end strap around the rolled mattress to prevent unrolling.
4. Store mattress and pump in a dust-free environment with no exposure to direct sunlight.

▲ **NOTICE: Do not fold, crease or stack the mattress.**

TROUBLESHOOTING

Problem	Solution
Power is not ON	• Ensure the plug is connected to a power source. • Check if fuse is blown.
Alarm is on (Audible & visible)	• Check if power has suddenly shut off. • Ensure the CPR is sealed. • Ensure connection between air tube connector and pump unit is secure. • Ensure all tubing connections along mattress are secure.
Patient is bottoming out	• Pressure setting might be inadequate for patient; adjust comfort range one to two levels higher and wait a few minutes for maximum comfort
Mattress form is loose	• Ensure all snap buttons and mattress straps are securely fastened. • Ensure mattress is fixed to bed frame by straps.
No air produced from some air outlets of the air tube connector	• This is normal since there is alternating mode. Air outlets take turns to produce air during their cycle time.
If the problem still occurs, contact your Graham-Field authorized distributor	

SERVICE

If a problem occurs with the SIMMONS™ Clinical Care 765000S Clinical Plus Alternating Pressure Mattress System with Active Sensor Technology that you are unable to resolve, contact your Graham-Field authorized distributor for service.

SPECIFICATIONS

Pump		Specification
Power Supply (Info: see rating label on product)		AC 120V 60 Hz 0.17A (for 120V system)
Fuse Rating		T1A, 250V
Cycle time		Fixed / 10 minutes
Dimensions (L x W x H)		11.4" x 7.9" x 4.6" (29.1 x 20 x 11.7 cm)
Weight		5 lb (2.2 kg)
Environment	Temperature	Operation: 50°F to 104°F (10°C to 40°C) Storage: 5°F to 122°F (-15°C to 50°C) Shipping: 5°F to 158°F (-15°C to 70°C)
	Humidity	Operation: 10% to 90% non-condensing Storage: 10% to 90% non-condensing Shipping: 10% to 90% non-condensing
Classification		Class II with functional earth, Type BF, IPX0 Applied Part: Air Mattress Not suitable for use in the presence of a flammable anesthetic mixture (No AP or APG protection)

Mattress	Specification
Dimensions (L x W x H)	78.7" x 35.4" x 8" (200 x 90 x 20.3 cm)

ONE (1) YEAR LIMITED WARRANTY

SCOPE OF WARRANTY

GF Health Products, Inc. ("GF") warrants to the original purchaser only that it will replace or repair components, at GF's sole discretion, that are defective in material or workmanship under normal use and service. All warranties are conditioned upon the proper use of the products strictly in accordance with good commercial practice and applicable GF instructions and manuals, including proper use and maintenance. To the extent that a component is warranted by a third party, GF conveys all of its rights under that warranty to the original purchaser, to the extent permitted. This limited warranty shall only apply to defects that are reported to GF's customer service team within the applicable warranty period and which, upon examination by GF or its authorized representative, prove to be a warranty item. This limited warranty is not transferable.

The warranted components and time period are set forth below:

SIMMONS™ Clinical Care 765000S Clinical Plus
Alternating Pressure Mattress System with Active Sensor Technology: one year

The applicable warranty period shall commence from date of shipment to the original customer, unless there is an expiration date on the component in which case the warranty shall expire on the earlier of warranty period or the expiration date.

OBTAINING WARRANTY SERVICE

A GF Customer Service Representative must authorize warranty service. Please contact the GF Customer Service department by calling 678-291-3207, sending a fax request to 770-368-2386 or by e-mailing a request to cs@grahamfield.com. Specific directions will be provided by the Customer Service Representative. Failure to abide by the specific directions will result in denial of the warranty claim.

EXCLUSIONS

The warranty does not cover and GF shall not be liable for the following:

1) Defects, damage, or other conditions caused, in whole or in part, by misuse, abuse, negligence, alteration, accident, freight damage, tampering or failure to seek and obtain repair or replacement in a timely manner;
2) Products which are not installed, used, or properly cleaned and maintained as required in the official manual for the applicable product;
3) Products considered to be of a non-durable nature including, but not limited to: casters, filters, fuses, gaskets, lubricants, and charts;
4) Accessories or parts not provided by GF;
5) Charges by anyone for adjustments, repairs, replacement parts, installation or other work performed upon or in connection with such products which are not expressly authorized in writing, in advance, by GF;
6) Any labor or shipping charges incurred in the replacement part installation or repair;
7) Costs and expenses of regular maintenance and cleaning; and
8) Representations and warranties made by any person or entity other than GF.

ENTIRE WARRANTY, EXCLUSIVE REMEDY AND CONSEQUENTIAL DAMAGES DISCLAIMER

THIS WARRANTY IS GF'S ONLY WARRANTY AND IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED. GF MAKES NO IMPLIED WARRANTIES OF ANY KIND INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

IF ANY MODEL OR SAMPLE WAS SHOWN TO THE CUSTOMER, SUCH MODEL OR SAMPLE WAS USED MERELY TO ILLUSTRATE THE GENERAL TYPE AND QUALITY OF THE PRODUCT AND NOT TO REPRESENT THAT THE PRODUCT WOULD NECESSARILY CONFORM TO THE MODEL OR SAMPLE IN ALL RESPECTS.

THIS WARRANTY IS LIMITED TO THE REPAIR OR REPLACEMENT OF THE DEFECTIVE PARTS. GF SHALL NOT BE LIABLE FOR AND HEREBY DISCLAIMS ANY DIRECT, SPECIAL, INDIRECT, INCIDENTAL, EXEMPLARY OR CONSEQUENTIAL DAMAGES, INCLUDING, BUT NOT LIMITED TO: DAMAGES FOR LOSS OF PROFITS OR INCOME, LOSS OF USE, DOWNTIME, COVER, OR EMPLOYEE OR INDEPENDENT CONTRACTOR WAGES, PAYMENTS AND BENEFITS.

The warranties contained herein contain all the representations and warranties with respect to the subject matter of this document, and supersede all prior negotiations, agreements and understandings with respect thereto. The recipient of this document hereby acknowledges and represents that it has not relied on any representation, assertion, guarantee, warranty, collateral contract or other assurance, except those set out in this document.

For additional information on this product or this warranty, please contact a GF Customer Service Representative.

NOTES:

1) Additional terms and conditions may apply.
2) Freight claims must be notated on the Bill of Lading and must be made with immediacy. The ICC regulations govern specific requirements for freight claims. Failure to abide by those regulations may result in a denial of the freight claim. GF will assist you in filing the freight claim.
3) Claims for any short shipment must be made within thirty (30) days of the invoice date.

GF Health Products, Inc.
2935 Northeast Parkway
Atlanta, GA 30360
Tel 770-368-4700
Fax 770-368-2386
www.grahamfield.com

APPENDIX A: EMC INFORMATION

Guidance and Manufacturer's Declaration- Electromagnetic Emissions:

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment-Guidance
RF emissions CISPR 11	Group1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network.
Harmonic emissions IEC61000-3-2	Class A	
Voltage fluctuations / Flicker emissions IEC61000-3-3	Complies	

Guidance and Manufacturer's Declaration- Electromagnetic Immunity:

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Immunity Test	IEC60601 Test Level	Compliance	Electromagnetic Environment-Guidance
Electrostatic Discharge (ESD) IEC61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC61000-4-4	±2kV for power supply line ±1kV for input/out line	±2kV for power supply line ±1kV for input/out line	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	<5 % U_T (>95 % dip in U_T)for 0,5 cycle 40 % U_T (60 % dip in U_T)for 5 cycles 70 % U_T (30 % dip in U_T)for 25 cycles <5 % U_T (>95 % dip in U_T)for 5 sec	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of this device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to the application of the test level			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity:

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Immunity Test	IEC60601 test level	Compliance	Electromagnetic Environment-Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of this device, including cables, than there commended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2\sqrt{P}$ 150kHz to 80MHz $d=1.2\sqrt{P}$ 150kHz to 80MHz $d=2.3\sqrt{P}$ 80 MHz to 2.5G MHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).[b]
Conducted RF IEC 61000-4-6	3Vrms150 kHz to 80 MHz outside ISM bands[a]	3 Vrms	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [c], should be less than the compliance level in each frequency range[d].
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz;13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

b) The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

c) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

d) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and this device:

This device is intended for use in an electromagnetic environment in which radiated RF disturbances ar controlled. The customer or the user of this device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this device as recommended below, according to the maximum output power of the communications equipment

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Manufactured for:
GF Health Products, Inc.
2935 Northeast Parkway
Atlanta, Georgia 30360

telephone: 770-368-4700
fax: 770-368-2386

GRAHAM-FIELD®

www.grahamfield.com

© 2013 GF Health Products, Inc.

Made in Taiwan